No. 23-2989

IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

UNITED STATES OF AMERICA,
Plaintiff-Appellee,

v.

MARK SCHENA,
Defendant-Appellant.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT FOR
THE NORTHERN DISTRICT OF CALIFORNIA, NO. 20-CR-425
(THE HONORABLE EDWARD J. DAVILA, UNITED STATES DISTRICT JUDGE)

ANSWERING BRIEF FOR THE UNITED STATES

ISMAIL J. RAMSEY
United States Attorney

CHRISTINA LIU
Assistant United States Attorney
Northern District of California

JACOB FOSTER
Principal Deputy Assistant Chief

LAURA CONNELLY
Trial Attorney
Fraud Section, Criminal Division

NICOLE M. ARGENTIERI
Principal Deputy Assistant Attorney General

LISA H. MILLER
Deputy Assistant Attorney General

SOFIA M. VICKERY
Attorney, Appellate Section
Criminal Division
U.S. Department of Justice
950 Pennsylvania Ave., N.W.
Washington, DC 20530
(202) 305-7408
Sofia.Vickery@usdoj.gov

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Statutes and Rules

Other Authorities

JURISDICTION AND BAIL STATUS

Mark Schena appeals his judgment of conviction. The district court had jurisdiction under 18 U.S.C. § 3231 and entered final judgment on November 17, 2023. 1-ER-2-9.[1] Schena filed a timely notice of appeal. 10-ER-2685. This Court has jurisdiction under 28 U.S.C. § 1291 and 18 U.S.C. § 3742(a). Schena is in custody with a projected release date of September 16, 2030.

ISSUES PRESENTED

1. Whether the district court correctly denied Schena's motion to dismiss charges under the Eliminating Kickbacks in Recovery Act ("EKRA"), 18 U.S.C. § 220(a)(2)(A).

2. Whether the district court properly admitted testimony about insurance policies and Schena's knowledge of EKRA.

3. Whether the district court plainly erred in instructing the jury on the required mental state for the healthcare-fraud and EKRA violations.

4. Whether sufficient evidence supported Schena's securities-fraud convictions.

5. Whether the district court clearly erred in ordering $24,289,540 in restitution and a $2,727,240 forfeiture-money judgment.

---

[1] "ER" refers to Schena's Excerpts of Record. "SER" refers to the government's Supplemental Excerpts of Record. "Br." refers to Schena's opening brief.

STATEMENT OF THE CASE

I. Procedural History

Following a jury trial, Schena was convicted of conspiring to commit healthcare and wire fraud, in violation of 18 U.S.C. § 1349 (Count 1); two counts of healthcare fraud, in violation of 18 U.S.C. §§ 1347, 2 (Counts 2-3); conspiring to pay illegal kickbacks, in violation of 18 U.S.C. § 371 (Count 4); two counts of paying illegal kickbacks, in violation of 18 U.S.C. §§ 220(a)(2)(A), 2 (Counts 5-6); and three counts of securities fraud, in violation of 15 U.S.C. § 78j, 17 C.F.R. § 240.10b-5, and 18 U.S.C. § 2 (Counts 7-9). 1-ER-2. The district court sentenced Schena to 96 months of imprisonment, ordered $24,289,540.95 in restitution, and entered a $2,727,240 forfeiture-money judgment. 1-ER-3, 11, 237-238.[2]

II. Offense Conduct

Schena, the self-proclaimed "father of microarray technology" and president of Arrayit, claimed that Arrayit's miniaturized laboratory test could detect 120 allergens and COVID-19 from four drops of blood. Schena falsely and fraudulently billed health insurers for these tests; paid illegal kickbacks to induce patient referrals to Arrayit; and repeatedly lied to investors and the public to increase Arrayit's stock price.

At trial, the jury heard the testimony of Arrayit employees; marketers; investors; public health professionals; law enforcement agents; and experts in Medicare and

[2] The jury returned a Count One special verdict finding Schena guilty of both healthcare and wire-fraud conspiracy. 2-ER-291.

financial securities. Additionally, the jury saw marketing materials, text messages, emails, press releases, tweets, contracts, and billing records. Based on this evidence, the jury found Schena guilty.

A. Faced with a failed manufacturing business, Schena moved Arrayit to Silicon Valley and began performing allergy tests.

Schena was the president and "boss" of Arrayit, a small manufacturing company selling microarray tools from a California strip mall that employed about six people. 4-ER-1058; 5-ER-1168-1169, 1172-1174. By 2017, Arrayit was "on the verge of bankruptcy and collapse," unable to pay suppliers or its own employees. 5-ER-1173-1175.

But Schena had a plan. Schena had an "obsession" with medical-billing codes and believed Arrayit could make "[h]undreds of millions" of dollars billing insurance for a new allergy test. 3-ER-631-632; 6-ER-1488. To impress investors, Arrayit moved to a "huge," "over the top" Silicon Valley laboratory with a $30,000 monthly rent. 3-ER-750; 5-ER-1173. Schena offered his house as collateral for a loan, promising to repay it with proceeds from the new allergy test. 5-ER-1175-1178.

Arrayit's new test purported to use microarray technology to test for 120 allergens using four drops of blood. Each test cost Arrayit about one dollar to run, but Schena believed that Arrayit could bill insurance up to $10,000 per test. 3-ER-655; 6-ER-1685. Even though Arrayit did not have necessary regulatory approvals, it began performing tests. 3-ER-622-623; 5-ER-1212-1214. Schena and the head of another

laboratory agreed to bill insurance for Arrayit's tests under the other lab's name. 3-ER-623; 5-ER-1214. As Schena put it, "[w]e need the money." 5-ER-1214.

B. Schena lied to regulators and insurers to get approvals for Arrayit to bill for its allergy test.

For Schena's vision to work, it was an "absolute necessity" that Arrayit bill insurance companies. 3-ER-631. Before Arrayit could enroll with insurers, it needed a California Clinical Laboratory License and a Clinical Laboratory Improvement Amendments (CLIA) certificate. 2-ER-375, 378; 5-ER-1213; 6-ER-1512. Schena lied to obtain those regulatory approvals. 5-ER-1213.

The State of California initially denied Schena's license application. 6-ER-1528. Regulations required a licensed laboratory director and licensed clinical-laboratory scientist. 6-ER-1513-1516. The lab director oversees the lab's operation and administration. 6-ER-1514. When the examiner asked for the email of Arrayit's lab director, Schena gave the "very unusual" response that he did not have it. 6-ER-1521. During the in-person inspection, the examiner noticed that the space seemed relatively empty and that Schena, not a lab director, showed her the lab. 6-ER-1521-1522, 1524. When the examiner told Schena that he was not qualified to be lab director, Schena became "very upset," threw a binder, and left the meeting. 5-ER-1221; 6-ER-1524-1525. After sending Schena multiple letters identifying deficiencies, in April 2017, the examiner denied Arrayit's application. 6-ER-1527-1528. And for the first time in her career, the examiner decided not to inspect Arrayit alone again. 6-ER-1525-1526.

Two months later, Schena successfully reapplied for a laboratory license. 6-ER-1528, 1532. The examiner had made it "very clear" that Arrayit needed a licensed lab director and licensed clinical-laboratory scientist. 6-ER-1530-1531. In this application, Schena represented that a licensed lab director and clinical-laboratory scientist would perform all testing. 6-ER-1530-1531. Schena further represented that Arrayit's lab director, Dr. Julie Taguchi, would be responsible for Arrayit's operation and administration, the testing-method verification, and ensuring that a licensed supervisor was always available. 6-ER-1532-1533. Relying on those representations, the examiner granted Arrayit a license. 6-ER-1532.

Schena's representations were lies. 6-ER-1660-1663. Taguchi was an oncologist in Santa Barbara who "blanketly" trusted Schena. 6-ER-1650, 1679; 8-ER-2190. Schena told Taguchi that the lab-director position was not "very hard"; she only had to work a half-day every three months and visit the lab quarterly to sign papers. 6-ER-1649-1650. Accordingly, Taguchi visited Arrayit two to four times annually and signed papers that Schena handed her, "most of the time" without knowing what she was signing. 6-ER-1654-1655, 1724. Schena never told Taguchi that she was responsible for Arrayit's operation and administration, test verifications, or supervision. 6-ER-1514, 1649-1650. The person who actually performed the lab-director tasks was Schena, not Taguchi. 5-ER-1215.

Schena next applied for a CLIA certificate. This certificate ensures that a laboratory is properly licensed with licensed personnel performing tests. 2-ER-376; 6-

ER-1516. Schena's first application was denied after the accrediting organization learned that unlicensed personnel performed Arrayit's tests. 6-ER-1535. Yet a couple of years later, Schena obtained the CLIA certificate from a state agency. 6-ER-1556-1557. Schena was so happy that he asked Taguchi to videotape him being sprayed with champagne. 3-ER-633; 6-ER-1664-1665. The CLIA certificate was "a big buzz" because Arrayit could now enroll in insurance programs. 2-ER-378; 3-ER-633.

Finally, Arrayit enrolled with healthcare-benefit programs like Medicare, which is funded primarily by tax dollars and provides health insurance for individuals over age 65, and Blue Shield of California, a private insurer. 2-ER-370, 393; 7-ER-1865, 1871. These are trust-based systems that rely on enrolled providers to submit accurate information. 2-ER-404-405; 7-ER-1873-1874. In its enrollment applications, Arrayit agreed to not submit false or fraudulent claims and to follow all applicable rules and regulations, including the requirement that services be medically necessary and prohibitions on kickbacks. 2-ER-388, 395-398; 7-ER-1868-1869. Arrayit's applications also included copies of the CLIA certificate listing Taguchi as lab director. 2-ER-380; 7-ER-1870-1871. These representations bound anyone affiliated with Arrayit. 2-ER-393.

A laboratory is ultimately responsible for its insurance claims, regardless of whether the service was ordered by a doctor or whether the laboratory used a billing company. 2-ER-405-406, 461; 7-ER-1874-1875. When a provider receives payments from Medicare, it agrees that it has complied with all applicable rules and regulations.

2-ER-406. If a healthcare-benefit program learned that a provider submitted false information, claimed a medically unnecessary service, or violated anti-kickback provisions, the program would not pay the claim. 2-ER-401, 412-413; 7-ER-1877.

C. To get patients, Schena lied about Arrayit's allergy test.

To make millions billing insurance, Schena needed a "large influx" of patients. 3-ER-632. Arrayit's marketing strategy started with Schena, who also ultimately approved marketing messages. 3-ER-630-631, 635. At Schena's direction, individuals marketing Arrayit's allergy tests targeted doctors like chiropractors, naturopaths, or small family groups lacking allergy experience. 3-ER-645-646, 648-649; 5-ER-1237. Schena perceived those doctors as "naïve" or "low hanging fruit," susceptible to deceptive marketing pitches. 3-ER-645-646. Arrayit's marketers "stayed away" from allergy specialists because they were "completely opposed" to or "upset" about Arrayit's test. 3-ER-645-646; 5-ER-1237.

Schena deployed two deceptive pitches. First, marketers would say that Arrayit's blood test was "highly accurate" and "far superior" to skin testing. 3-ER-653-654, 666; 5-ER-1251. But that was not true. Allergy specialists view skin-allergy tests as the "gold standard" and blood-allergy tests as a last resort. 2-ER-410; 3-ER-646, 655. Unlike a skin test, a blood test measures antibodies, which indicates prior exposure to an allergen but does not predict allergic reactions. 2-ER-496-497. For example, a blood test showing peanut antibodies means that the patient has prior exposure to peanuts, not that the patient will experience an allergic reaction. 2-ER-497. Schena "belittled" and

dismissed "constant complaints" that Arrayit's test failed to indicate a known allergy or identified an allergy that did not exist. 3-ER-667-668; 5-ER-1193, 1250-1251.

Schena's second "very important" marketing point was that Arrayit's test was financially lucrative for doctors. 3-ER-649-650, 748-750; 5-ER-1249. Because it tested 120 allergens, Arrayit's test was likely to indicate some allergy, giving doctors an "easy way" to justify immunotherapy treatment. 3-ER-652-653. To make it even easier, Arrayit developed a one-click option for doctors to order immunotherapy. 3-ER-649-651. Doctors were told they could make up to a million dollars annually by ordering immunotherapy justified by Arrayit's test. 3-ER-650-651.

But it is not medically necessary to test all patients for 120 allergens. 3-ER-658-659; 5-ER-1242-1243, 1247. Schena had picked the number 120 not for any medical reason but because it matched the slots in an array machine. 2-ER-498-499. The 120 allergens then were "backfilled" with numerous food and environmental allergens, including plants found only in certain regions of the United States. 2-ER-498-499; 3-ER-658. Schena ignored warnings that it was "wrong" and medically unnecessary to test every patient for 120 allergens. 3-ER-658-660; 5-ER-1245-1247. For this blood test, Arrayit billed insurance thousands more dollars than a traditional skin-allergy test. 2-ER-496, 502. Schena was "very excited" about the 120-allergen design because it allowed Arrayit to bill insurance for each allergen, up to $10,000 per test. 3-ER-656; 5-ER-1238; 6-ER-1479-1481.

D. Schena paid kickbacks for referrals to generate additional patients.

To generate more patients, Schena paid marketers a percentage of the insurance reimbursement for each patient that the marketer brought to Arrayit. 5-ER-1162, 1211-1213, 1222. Arrayit did not pay its marketers a salary, did not pay for hours worked, and did not pay for general marketing activities. 3-ER-636; 5-ER-1222-1223. For example, Schena told some marketers they would get 50% of insurance reimbursements, describing the arrangement as "[a] few years of selling" and then "relaxing in the Caribbean." 5-ER-1211. In turn, marketers steered patients to Arrayit by pitching doctors with Schena's deceptive marketing strategies. Once a marketer successfully pitched a doctor, the marketer "controlled" where that doctor's blood samples would go. 3-ER-637. The marketers sent those samples to Arrayit, sometimes without even telling the doctor that other options existed. 2-ER-503; 3-ER-637; 5-ER-1222-1223.

In October 2018, the Eliminating Kickbacks in Recovery Act (EKRA) went into effect. 2-ER-366; 3-ER-637. EKRA was "[m]onumental" and "industry changing" because the law made it illegal for laboratories to pay a percentage of insurance reimbursements for patient referrals. 2-ER-491-492; 3-ER-637; 5-ER-1223. In response, laboratories around the country converted marketers to salaried employees. 3-ER-636-638.

Four months after EKRA went into effect, Schena helped create the first written contract for Arrayit's marketers. 5-ER-1227. Schena specifically wanted a statement

that the marketer agreed to abide by EKRA, which the contract described as "mak[ing] it a criminal offense to offer or receive a kickback in an exchange in order to induce a referral to a … clinical laboratory." 5-ER-1228. But Schena also wanted the new contract to be silent as to how Arrayit actually paid marketers. 5-ER-1230. That was because Schena specifically did *not* want to disclose that Arrayit still paid marketers a percentage of insurance reimbursements. 5-ER-1230.

Multiple people told Schena that Arrayit's payments violated EKRA. 2-ER-494; 3-ER-761-762; 5-ER-1224-1227. For example, Marc Jablonski, Arrayit's "number one marketer," asked Schena to change his payment structure to comply with EKRA. 3-ER-629, 638-640. At that point, Schena and Jablonski had a verbal agreement that Jablonski would receive 20% of insurance reimbursements for patients he brought to Arrayit. 3-ER-627-628. Arrayit sent Jablonski a monthly spreadsheet listing blood samples that Jablonski brought to Arrayit, the amount that insurance paid, and a calculation showing his 20% cut, followed by a wire transfer for that amount. 3-ER-642-643, 645.

In response, Schena claimed that Arrayit did not have enough money for salaried employees and that EKRA "wasn't a big deal." 3-ER-638-640; 5-ER-1225. Jablonski, who made up to $20,000 monthly, continued with this arrangement even though it was "very clear" that his payments violated EKRA. 3-ER-621, 660, 761. On December 16, 2019, Arrayit wired Jablonski $19,289.74. 3-ER-641-642. That payment corresponded to 20% of insurance reimbursements for patients that Jablonski brought to Arrayit. 3-

ER-642-644. Similarly, on April 17, 2020, Arrayit wired Jablonski $6,650.58—reflecting 20% of insurance payments for patients that Jablonski brought to Arrayit that month. 3-ER-644-645.

Schena had a different arrangement with Madan Mohan, a medical clinic owner. 5-ER-1261-1262. Mohan collected and sent blood samples to Arrayit for testing and then billed insurance as though Mohan's clinic had run the test. 5-ER-1262. In return, Arrayit paid Mohan 50% of the insurance reimbursements. 5-ER-1262.

Finally, Arrayit paid Taguchi, the lab director, almost $10,000 that Taguchi wrongly believed was her consulting fee but, in fact, was insurance reimbursements. 6-ER-1693-1697. Because Schena offered her free Arrayit allergy testing, Taguchi occasionally ordered tests for her patients without considering whether insurance would consider them medically necessary. 6-ER-1692; 7-ER-1814. She later was "horrified" to learn that, between October 2018 and June 2020, Arrayit billed insurance using her provider number on 43 different occasions. 6-ER-1697-1698; 8-ER-2180, 2188-2189.

E. Schena bundled Arrayit's allergy test with a COVID-19 test to generate additional business.

In March 2020, the government announced the COVID-19 pandemic and people stayed home. 2-ER-414; 5-ER-1251. Arrayit's testing numbers dropped suddenly. 5-ER-1251. In Schena's words, "[w]e need to get tests in here." 5-ER-1251.

People were "frantic" for COVID tests, and within a few weeks, Schena announced that Arrayit had one. 5-ER-1252-1255. Arrayit's COVID test used the

same fingerstick procedure as the allergy test; the "whole purpose" was to get blood samples so that Arrayit could also run allergy tests on them. 5-ER-1260-1261, 1267. Arrayit's test-requisition form provided a COVID-only option, but Schena told marketers to pitch doctors to "check all" testing boxes. 3-ER-681-682; 5-ER-1266. This pitch included a quote falsely attributed to Dr. Anthony Fauci stating that COVID and allergy can be confused. 5-ER-1266-1267. Regardless of what was checked on the form, Schena directed employees to run allergy tests on "all" blood samples. 5-ER-1270. Schena sought to "bundle[]" the COVID test, which paid "nothing," with the lucrative allergy test. 3-ER-681-684. Thus, if a patient got a COVID test, "like it or not," the patient also got an allergy test. 3-ER-681.

Schena told marketers to pitch Arrayit's test as the "go-to" assessment for current COVID infection that was "as good or better than" a PCR test. 3-ER-678; 5-ER-1260. But Arrayit's test measured COVID antibodies, showing only prior exposure to the COVID virus, while a PCR test is the "gold standard" to detect current infection. 3-ER-677; 5-ER-1259; 7-ER-1905. Schena also told marketers to say that Arrayit's test provided results within 48 hours, an important feature for concerned patients; in reality, it took up to three weeks. 3-ER-685-686; 5-ER-1259.

On one occasion, a marketer (Jablonski) arranged for Arrayit's COVID tests to be used by a rural Arizona school district. 3-ER-687. Jablonski understood that Arrayit would run allergy tests on the collected blood samples and pay him a percentage of the insurance reimbursements. 3-ER-688. After the event, a "backlash" occurred with

participants upset about inaccurate and delayed results and that Arrayit had run allergy tests on their blood samples. 3-ER-688-690.

For example, one teacher, W.W., drove 40 miles to get tested. 6-ER-1587-1588. When W.W. saw allergy questions on the intake form, she was "adamant" that she did not want or need an allergy test and wrote "COVID test only." 6-ER-1588-1589. W.W. received a negative COVID result, which she believed was inaccurate. 6-ER-1591. W.W. also received allergy-test results and multiple phone calls about immunotherapy. 6-ER-1591-1592. Arrayit subsequently billed W.W.'s private insurance $5,293.28 for the allergy test, and the insurer paid that claim. 6-ER-1583-1584, 1590; 8-ER-2200.

On another occasion, T.R. accompanied a friend to a construction-job interview in San Jose. 7-ER-1975. When they arrived, T.R. and her friend were told that a COVID test was required and directed to fill out a form with personal and health-insurance information. 7-ER-1976-1977. T.R. received a finger prick, which she was told would test for COVID. 7-ER-1979. She was never told about and did not consent to allergy tests. 7-ER-1980-1981, 1984. Arrayit billed Medicare $5,293.28 for an allergy test for T.R., and Medicare paid that claim. 2-ER-419; 8-ER-2201. T.R. never received the results of the COVID test. 7-ER-1982-1983.

F. Arrayit billed insurers over $77 million for allergy tests.

Arrayit's cash flow increased "exponentially" in a "classic sort of hockey stick curve." 3-ER-633-634. Between October 2018 and June 2020, Arrayit billed Medicaid, Medicare, and private insurers over $77 million. 8-ER-2179-2181. Arrayit collected

over $2.7 million on those claims, a difference reflecting that some claims were never paid, and others were paid at a lower amount. 8-ER-2181.

Arrayit billed over 99% of its insurance claims for $5,216, corresponding to the reimbursement rate for a 62-allergen test. 8-ER-2183-2184. Medicare policy, which sets national standards, requires that allergy testing be specific to individual patients and reimburses per tested allergen, up to 62 allergens. 2-ER-416, 418-419. That Arrayit billed the exact same number of allergens for nearly every patient is an indication of fraud. 2-ER-418. Blue Shield identified Arrayit as billing "a very excessive number of allergens," investigated the company, and sought a refund of claims paid. 7-ER-1880-1886. Among U.S. laboratories, Arrayit ranked first in the amount billed to Medicare per patient for allergy tests, billing thousands of dollars more per patient than its peers. 8-ER-2186; 1-SER-261.

G. Schena lied to prop up Arrayit's stock.

Arrayit was a publicly traded company with "penny" or "over-the-counter" stock, meaning that its stock traded at relatively low prices and volumes. 3-ER-779-780, 790-791. In general, stock price depends on how investors value a company. 3-ER-781. The price generally increases on positive news and decreases on negative news. 3-ER-781-782. Officers of public companies have a duty to shareholders to be honest and avoid material misrepresentations or omissions. 3-ER-785.

Schena was "absolutely obsessed" with Arrayit's stock—he talked about it "all of the time," saying, "[w]e are all going to be billionaires." 5-ER-1172, 1183. Schena

personally owned over 12 million shares; if Arrayit's stock went up, the value of his shares also increased. 8-ER-2258-2259. Schena wanted investors to keep buying Arrayit stock to drive up its price. 5-ER-1183. Schena tried to "emulate[]" Elizabeth Holmes and Steve Jobs. 5-ER-1185. Investors were told that Schena was "the father of microarray technology," on the "short list for the Nobel Prize," and "going to save the world with microarrays." 5-ER-1185. Schena told investors that Arrayit would be worth "billions" and that he would "cure all medical illness within 50 years using the microarray." 5-ER-1181, 1195.

Arrayit was delinquent in filing audited financial statements with the Securities and Exchange Commission (SEC), but Schena repeatedly reassured investors that Arrayit would release the statements soon. In June 2017 and 2018, Arrayit tweeted that it had provided "all" outstanding audit items and that auditors were running necessary calculations; in September 2018, Arrayit tweeted that it would release financials that "fall"; in October 2018, Arrayit tweeted about a "quiet period" for financials through 2018, suggesting that they would be released soon; and in December 2018, Arrayit wrote that it file financials "in the coming quarter." 3-ER-828-832. Schena personally confirmed that release date, writing on March 30, 2019, that Arrayit's "financial team is working this weekend." 3-ER-833-838. But the next day, Arrayit tweeted only that it would file financials "as quickly as possible." 3-ER-840-842. Schena responded to angry messages ("You're going to prison. You're a fraud") with bland assurances thanking investors for their "feedback" and "good humor." 3-ER-843, 845-846

Arrayit never released financial statements. 3-ER-838-839. Arrayit had engaged a public accounting firm to audit its 2014-2017 statements, but the firm could not complete the audit because Arrayit failed to provide necessary information. 4-ER-979-980. The partner overseeing the audit described Arrayit as the most unresponsive client of his career and believed that Schena did not want the audits completed. 4-ER-980-981, 1033. Arrayit never engaged the firm to audit 2018 statements. 4-ER-977.

In the absence of SEC filings, investors looked to Arrayit's official communications. 4-ER-958; 5-ER-1346-1347. Schena emailed with investors, decided the content of press releases, and controlled Arrayit's twitter account. 5-ER-1188, 1195, 1334-1335. Schena tried to issue a press release every Monday. 5-ER-1195-1196. The "formulaic Mark Schena press release" implied something without much detail and then pivoted to impressive statistics about another company. 5-ER-1196, 1203. Schena's twitter strategy was similar: say something about another company and include an impressive photo. 5-ER-1198-1199. For example, in 2015, Arrayit linked to a children's hospital, tweeting that its microarray was "accelerating pediatric diagnostics," but the machine Arrayit provided the hospital did not work. 2-ER-562-565. Similarly, in 2017 and 2018, Arrayit tweeted about $2.5 million in requests from the Department of Veterans Affairs, but Arrayit had never received any such inquiries. 4-ER-1065-1073. Schena's communications often were posted to the ihub online message board. 4-ER-861-862, 938-939. Schena talked about ihub "[a]ll the time" and had it bookmarked on his cellphone. 3-ER-805-806; 5-ER-1170. When a company is delinquent with SEC

filings and public information is otherwise scant, message boards like ihub can have an "outsized effect" on stock price. 3-ER-783-785.

On November 19, 2018, an Arrayit press release "announce[d] an allergy testing agreement" with Sutter Health—"one of the nation's largest healthcare networks" with $12 billion in annual revenue. 3-ER-813-814; 1-SER-262. This press release was "huge" for investors. 4-ER-949. But Arrayit did not have an agreement with Sutter Health, which responded with a cease-and-desist letter. 4-ER-1040-1041, 1051. Schena agreed to cease using Sutter Health trademarks. 4-ER-1042. Yet about four months later, a tweet declared that "[i]n November 2018, Arrayit began providing allergy testing services to a major health care consortium" and linked to the earlier Sutter Health release. 3-ER-817. Multiple people emailed Schena with congratulations and questions about this "deal," but he never corrected the lie. 3-ER-818-821.

On August 8, 2019, a tweet announced that Arrayit "commences $240,000,000 test kit manufacturing run to build inventory for our rapidly expanding physician-ordered finger stick allergy testing services." 3-ER-822-823; 1-SER-263. As one investor explained, this tweet was reassuring evidence of Arrayit's revenue in the absence of financial statements. 6-ER-1627. But Arrayit spent less than $500,000 that entire quarter and its revenue never approached $240 million. 8-ER-2213-2214, 2218-2219. Yet Schena repeatedly confirmed a $240-million manufacturing run. 3-ER-823-828.

On March 21, 2020, Schena sent multiple emails stating that Arrayit had "received more than 50,000 requests for our fingerstick blood test for [COVID-19]" and was "coordinating with local, state, and federal agencies and with our distributors to make this test available to as many patients as possible on an expedited timeline." 4-ER-874-875. This language also appeared on ihub. 4-ER-876. Schena believed that if investors learned that Arrayit had a COVID test, stock would "go way up." 5-ER-1270-1271. In fact, one investor purchased tens of thousands of new shares after receiving Schena's email. 4-ER-956. The emails were false. As of that date, Arrayit had received only 842 emails regarding COVID-19, not 50,000 requests for its COVID test. 4-ER-880-881. Moreover, the company had only received COVID proteins a few days earlier, 6-ER-1563, 1568-1570, and lacked data on the validity of any COVID test. 5-ER-1257.

Arrayit first began running COVID tests in April 2020. 7-ER-2008. The Food and Drug Administration (FDA) allowed companies with a validated COVID test to begin marketing the test after formally notifying the FDA. 7-ER-1906-1907. On April 13, 2020, Arrayit notified the FDA of its COVID test. 7-ER-1910. The next day, Arrayit applied for emergency-use authorization. 7-ER-1913-1914. That application should have been "quite simple" because Arrayit presumably already had validated its test. 7-ER-1928-1929. Yet Arrayit's application was "very deficient," using, for example, the wrong performance benchmarks and allergy-testing documentation. 7-ER-1916-1917, 1926. On May 10, 2020, Arrayit submitted a second application for

emergency-use authorization, claiming its test was perfectly accurate but again failing to provide adequate information. 7-ER-1930-1934. The FDA never authorized Arrayit's COVID test. 7-ER-1936.

SUMMARY OF ARGUMENT

1. The district court correctly denied Schena's motion to dismiss the EKRA charges. As a legal matter, EKRA prohibits kickbacks to induce a referral even when the payment is made to someone other than the referring medical provider. The statute's text, history, and purpose undercut Schena's contrary claim. Moreover, even if Schena were correct, his argument raises a factual issue, not a legal one, and the trial evidence demonstrated that Schena made payments to individuals who referred patients to Arrayit.

2. The district court did not plainly err in admitting testimony about insurance policies or what witnesses told Schena about EKRA. This factual testimony was directly relevant to the jury's findings on whether Schena defrauded insurers and Schena's intent to violate EKRA. At no point did the witnesses testify about the law applicable to Schena's case or express legal opinions. Schena cannot show any error in admitting this testimony, much less a clear or obvious one. And given the district court's jury instructions and the overwhelming evidence of guilt, Schena also cannot show that any error affected substantial rights or the proceeding's fairness, integrity, or public reputation.

3. The district court properly instructed the jury on the mental state required for the healthcare-fraud and EKRA charges. The court explained that these offenses required that proof that Schena acted knowingly *and* willfully and correctly defined each term. Although a portion of the "knowingly" definition may have been inartful, a jury following the court's instructions would have necessarily (and correctly) determined whether Schena acted with a bad purpose. Moreover, the specific mens rea instructions on the conspiracy and healthcare-fraud charges (Counts 1-4) confirm that the guilty verdict reflected the jury's finding that Schena acted with the requisite intent. Particularly on plain-error review, the instructions adequately informed the jury that these offenses required that Schena acted with a bad purpose. Finally, any error did not affect substantial rights because the jury necessarily found, and the evidence overwhelmingly demonstrated, that Schena acted knowingly and willfully.

4. The evidence at trial—viewed in the light most favorable to the jury's verdict—proved that Schena committed securities fraud by making untrue statements of material facts. Ample evidence showed that the press release announcing an agreement with Sutter Health, the tweet announcing a $240-million-manufacturing run, and emails about Arrayit's COVID tests were false statements material to investors.

5. The district court did not clearly err in calculating restitution and forfeiture. The record amply supports the court's findings, under a preponderance-of-the-evidence standard, that insurers lost $2,772,240 and investors lost $21,562,300

because of Schena's healthcare and securities frauds. That the court calculated loss differently under the Sentencing Guidelines does not demonstrate clear error.

ARGUMENT

I. The district court correctly denied Schena's motion to dismiss the EKRA charges (Counts 4-6).

Schena contends (Br.35-47) that the district court erred in denying his motion to dismiss the EKRA counts charging him with conspiring to pay and paying illegal kickbacks. The court correctly denied the motion.

A. Background

Before trial, Schena argued that, as a legal matter, EKRA did not prohibit payments to marketers because the marketers did not themselves refer patients to Arrayit. 1-SER-255-260. The district court denied the motion. 1-ER-260-266. The court explained that EKRA contains "no requirement of 'directness'" and applies to payments made to "'induce'" referrals for laboratory services. 1-ER-265. The court found that the charged conduct "squarely falls within the text of EKRA" because "the marketers received a kickback to 'influence' the physician's referrals." 1-ER-266.

After trial, Schena moved for a judgment of acquittal or new trial, asserting insufficient evidence of a causal connection between the payments to Arrayit's marketers and referrals to Arrayit. 1-SER-59-60. The district court denied the motion. 1-SER-46-48. The court cited testimony that marketers conspired with Schena to receive kickbacks for inducing patient referrals; that the marketers induced referrals by

targeting "naïve" doctors with deceptive marketing; that after successfully pitching a doctor, the marketers decided where to send patient samples; and that the marketers sent samples to Arrayit to get kickbacks. 1-SER-47-48.

B. Standard of Review

This Court reviews de novo "a district court's decision whether to dismiss a charge in an indictment based on its interpretation of a federal statute." *United States v. Kelly*, 874 F.3d 1037, 1046 (9th Cir. 2017).

C. EKRA criminalizes kickbacks to intermediaries like marketers when the kickback is "to induce a referral."

1. The Eliminating Kickbacks in Recovery Act of 2018 (EKRA), Pub. L. No. 115-271, 132 Stat. 3894, 4108, makes it illegal to, "with respect to services covered by a health care benefit program," "pay[] or offer[] any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind[] to induce a referral of an individual to a … laboratory." 18 U.S.C. § 220(a)(2)(A). The parties agree that Arrayit's allergy tests were covered by a healthcare benefit program and that its payments to marketers and other individuals were intended "to induce a referral of an individual to a … laboratory." But Schena asserts (Br.35) that EKRA prohibits only "payments made to someone with the power to refer a patient to a lab." The district court correctly recognized that the statute contains no such limitation.

The starting point is the plain statutory text. *See Groff v. DeJoy*, 600 U.S. 447, 468 (2023) ("[S]tatutory interpretation must 'begi[n] with,' and ultimately heed, what a

statute actually says."). Nothing in Section 220(a)(2)(A) restricts the recipient of the remuneration, much less limits the subsection to only kickbacks paid to a referring medical provider. Courts also "resist reading words or elements into a statute that do not appear on its face." *Bates v. United States*, 522 U.S. 23, 29 (1997). This Court therefore should decline Schena's invitation (Br.37) to import into EKRA the "[i]mplicit" requirement that the "recipient of the kickback has the ability to make (or decide not to make) the referral." Here, the indictment charged Schena with paying "remuneration" to marketers "to induce a referral of an individual" by medical providers to Arrayit. EKRA's plain terms cover that charged conduct.

Other features of Section 220(a)(2)(A) reenforce its coverage of remuneration paid to induce a referral even when the remuneration is paid to an intermediary. *See Diaz v. United States*, 144 S. Ct. 1727, 1735 (2024) (emphasizing "a word's meaning is informed by its surrounding context" and a "crucial part of that context is the other words in the sentence"). The statute prohibits "*any* remuneration" and "*any* kickback," 18 U.S.C. § 220(a)(2) (emphasis added), which are word choices that "suggest[] a broad meaning," *Ali v. Federal Bureau of Prisons*, 552 U.S. 214, 218-219 (2008). The statute also specifies that remuneration is covered whether paid "directly or indirectly … to induce a referral." 18 U.S.C. § 220(a)(2)(A). The word "direct" means "stemming immediately from a source," and "indirect" means "not direct." *United States v. Prasad*, 18 F.4th 313, 325 (9th Cir. 2021); *see also id.* at 325-326 (explaining that "Congress's inclusion of the phrase 'directly or indirectly'" "indicates" that "the statute reaches broadly" (citing 18

U.S.C. § 982(a)(6)(A)(ii)(I))). Because a referral need not "stem[] immediately" from the payment, a kickback paid to an intermediary is covered even if it induces a referral indirectly. *Cf. United States v. Macapagal*, 56 F.4th 742, 745 (9th Cir. 2022) (interpreting 18 U.S.C. § 2422(b) and holding that a defendant may be guilty of knowingly inducing a minor to engage in sexual activity even when the defendant only communicated with an intermediary).

Legislative history points in the same direction. As initially proposed, this provision was limited to remuneration paid "directly or covertly … to … a person in exchange for the person referring an individual." 164 Cong. Rec. S5108 (July 19, 2018) (introducing bill); S.3254, 115th Cong., 2d Sess. (July 19, 2018). That the provision evolved to include remuneration paid "directly *or indirectly*" (emphasis added) and to eliminate language specifying the identity of the payee makes clear that Congress did not intend the enacted statute to contain those initial limitations. *See Russello v. United States*, 464 U.S. 16, 23-24 (1983) ("Where Congress includes limiting language in an earlier version of a bill but deletes it prior to enactment, it may be presumed that the limitation was not intended."). These revisions also accord with Congress's focus on "patient brokers" who profit by recruiting patients in exchange for a kickback from the treatment provider. *See* 164 Cong. Rec. S6097 (Sept. 6, 2018) (proposed amendment stating "sense of Congress" to "penalize" "patient brokers"). It would be anomalous to read a law designed to prohibit referrals incentivized by kickbacks paid to

intermediary brokers as criminalizing kickbacks only when paid directly to a referring medical provider.

2. Schena principally asserts (Br.36-39) that the concept of a kickback or bribe inherently requires that the kickback recipient be the same person who referred the patient. EKRA itself does not define "kickback," but other statutes with similar prohibitions are instructive. *Cf. Skilling v. United States*, 561 U.S. 358, 412 (2010) (explaining that prohibition on bribes and kickbacks in honest-services fraud statute, 18 U.S.C. § 1346, "draws content" from other federal statutes). A review of similar statutes prohibiting payments for specified favorable treatment confirms that the meaning of kickback or bribe does not include Schena's proposed limitation.

Some federal bribery and kickback statutes specifically disavow any limitation on the identity of the recipient. For example, the federal-institutions fraud statute, 18 U.S.C. § 215(a), makes it a crime to corruptly give "anything of value to *any person*, with intent to influence or reward [an enumerated person of a financial institution] in connection with [a specified business or transaction]." (emphasis added). *See* Br.37 (citing *United States v. Rodrigues*, 159 F.3d 439, 450 (9th Cir. 1998)). Similarly, the federal-programs bribery statute, 18 U.S.C. § 666(a)(2), prohibits corruptly giving anything of value "to *any person*, with intent to influence or reward [an agent of a state, local, or tribal government] in connection with [a specified business or transaction]." (emphasis added). This unambiguous language disproves Schena's assertion that a payment cannot be a kickback or bribe unless it is paid directly to the person from whom the

specified favorable treatment is sought. Like these statutes, EKRA prohibits kickbacks and bribes regardless of the identity of the payee so long as those payments are intended to induce a referral.

On the other hand, some statutes do specify the identity of the recipient. For example, in the Anti-Kickback Act, 41 U.S.C. § 8701(2), "kickback" means anything of value "provided *to a prime contractor, prime contractor employee, subcontractor, or subcontractor employee*" for specified favorable treatment (emphasis added). The Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)(2)(A), similarly makes it illegal to pay a kickback "to *any person* to induce *such person* to refer an individual …" (emphases added). *See* Br.37 (citing *United States v. Kats*, 871 F.2d 105, 108 n.2 (9th Cir. 1989) (per curiam)). But if Schena were correct that the word kickback already required that the recipient of a kickback be the person from whom the specified treatment is sought, the limitations in these statutes would be surplusage. *See United States, ex rel. Polansky v. Exec. Health Res., Inc.*, 599 U.S. 419, 432 (2023) ("'[E]very clause and word of a statute' should have meaning.").

Of course, Schena (Br.37) correctly notes that kickbacks "refer to 'a corrupt payoff' or 'a bribe.'" But he is incorrect (Br.37) in quoting a different EKRA subsection, 18 U.S.C. § 220(a)(1), to support the claim that EKRA prohibits only payments that "corruptly compensate someone 'in return for referring a patient.'" Schena was charged and convicted under 18 U.S.C. § 220(a)(2)(A), which prohibits payments not "in return for referring a patient" but "to induce a referral of an individual." Schena paid

kickbacks to marketers and others to induce a referral. As the district court recognized, that conduct "squarely falls within the text of EKRA." 1-ER-266. It also falls within the "ordinary understanding" (Br.43-44) of the corrupt payoff prohibited by EKRA.

3. Schena's reliance (Br.37, 39-42) on cases interpreting the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)(2)(A), is misplaced. To begin, Schena elides an important textual difference. As described above, the relevant provision of the Anti-Kickback Statute specifies the identity of the kickback recipient, prohibiting kickbacks paid "to *any person* to induce *such person* to refer an individual …" 42 U.S.C. § 1320a-7b(b)(2)(A) (emphasis added). Because EKRA contains no such restriction, decisions interpreting the Anti-Kickback Statute lack utility in this context.

Moreover, decisions interpreting the more restrictive Anti-Kickback Statute consistently reject the bright line urged by Schena. Instead, courts consider the specific evidence in each case about the substantive role of the kickback recipient, not the person's formal title. For example, the Fifth Circuit, which Schena cites (Br.39-41), "did not hold in [*United States v. Miles*, 360 F.3d 472, 480 (5th Cir. 2004)], that a payee with 'relevant decisionmaker' status is an independent, substantive requirement of the statute. Such a novel move would be tantamount to re-writing the statutory text." *United States v. Shoemaker*, 746 F.3d 614, 629 (5th Cir. 2014); *see also United States v. Marchetti*, 96 F.4th 818, 826 (5th Cir. 2024) ("We read our caselaw as a whole to say that the identity of the payee, while not essential, speaks to the intent of the payer."). These

cases show that the identity of the payee may be relevant for factual sufficiency but confirm that it is not a legal element of the statute.[3]

4. Schena's remaining arguments are unavailing. Schena's claims (Br.38-39, 43-44) of expansive liability under the government's interpretation are unfounded. By its terms, Section 220(a)(2)(A) is cabined to "remuneration," not general marketing efforts or commercial speech, and requires that remuneration be linked to inducement of specific referrals, not general performance pay. Here, the undisputed evidence showed that Arrayit paid kickbacks to marketers only when they induced a referral to Arrayit, not for hours worked or general marketing. *See* 3-ER-636; 5-ER-1162, 1211-1213, 1222-1223. To the extent a defendant in a different case might argue that payments were valid compensation, the jury could resolve that factual dispute.[4]

Finally, Schena cites (Br.41) an unpublished order in an employment lawsuit, *S&G Labs Hawaii, LLC v. Graves*, No. 19-cv-310, 2021 WL 4847430 (D. Haw. Oct. 18,

[3] The OIG Guidance cited by Schena (Br.42) similarly explains that liability "ultimately turns on a party's intent" and that one "useful" inquiry for that factual question is with whom the hospital has "remunerative relationship[s]." OIG Supplemental Compliance Program Guidance for Hospitals, 70 Fed. Reg. 4858, 4864 (Jan. 31, 2005).

[4] If, unlike Schena, a defendant had a sufficient factual basis, the district court could instruct the jury on EKRA's safe harbor. *See* 18 U.S.C. § 220(b)(2) (excluding payments to employees that "do[] not vary by (A) the number of individuals referred …; (B) the number of tests or procedures performed; or (C) the amount billed to or received from, in part or in whole, the health care benefit program …"). *Cf.* 8-ER-2138, 2287-2288 (rejecting Schena's safe-harbor-instruction request for lack of factual basis).

2021), discussing EKRA's application to an employment contract under which an employee was paid an annual base salary plus percentages of the monthly net profits for his client accounts. At the summary-judgment phase, the district court focused on the lack of evidence connecting the employee to individual patients, stating that the employee "was not paid to induce him to refer individuals." *Id.* at *2, *11-12. But as explained above, the EKRA prohibition is not restricted to only certain kickback recipients. As the district court recognized in denying Schena's motion, the statute "says nothing about payment needing to be made based on the 'direct' recruitment of an individual patient." 1-ER-265. And in any event, Schena has not claimed that the referrals here were unconnected to "individuals."[5]

D. Even under Schena's interpretation, the district court correctly refused to dismiss the indictment because Schena raised a factual issue, not a legal one.

Even if Schena were correct (Br.35) that EKRA criminalizes only "payments made to someone with the power to refer a patient to a lab," the district court *still* properly denied his pre-trial motion to dismiss. The consequence of Schena's argument would be that the government had to prove, as a factual matter, that Arrayit's marketers and the other kickback recipients had "the power to refer a patient to a lab." As the Anti-Kickback Statute cases discussed above demonstrate, this is a factual inquiry, not a legal element. But tellingly, Schena has not appealed the district court's denial of his

[5] This case is pending appeal in this Court (No. 24-823).

motions for a judgment of acquittal or new trial. 1-SER-46-48. To the extent Schena intended to challenge the trial evidence showing a causal link between the kickbacks and patient referrals, such an argument is undeveloped and should not be considered. *See United States v. Alonso*, 48 F.3d 1536, 1544 (9th Cir. 1995).

In any event, when viewed in the light most favorable to the verdict, *see Jackson v. Virginia*, 443 U.S. 307, 319 (1979), the trial evidence showed that Arrayit's marketers controlled patient blood samples and sent them to Arrayit. As directed by Schena, the marketers targeted "naïve" doctors without allergy experience. 3-ER-645-646, 648-649; 5-ER-1237. Jablonski, Arrayit's top marketer, testified that once he pitched a doctor, Jablonski "controlled" the blood samples. 3-ER-637. Another marketer explained that "when sales reps got their hands on the testing," the reps "went straight to the blood tests and didn't even tell the doctors about the skin testing." 2-ER-503. Although Schena characterizes this evidence (Br.44-45) as "boastful" or "vague," a reasonable juror could credit that testimony and find that the marketers steered patients to Arrayit. Moreover, the evidence showed that Mohan, the medical-clinic owner, collected samples and sent them to Arrayit in exchange for 50% of insurance reimbursements. 5-ER-1262. The undisputed evidence also showed that Arrayit paid Taguchi, Arrayit's supposed lab director, portions of insurance reimbursements after using her provider-identification number to bill insurance for patient tests. 6-ER-1696-1698; 8-ER-2180, 2188-2189. This record supplied ample evidence for the jury to find that the kickback recipients had authority to refer patients to Arrayit. *See United States v. George*, 900 F.3d

405, 411 (7th Cir. 2018) (affirming conviction of non-physician defendant); *United States v. Vernon*, 723 F.3d 1234, 1254 (11th Cir. 2013) (same).[6]

II. The district court did not plainly err in admitting testimony about insurance policies and what others told Schena about EKRA (Counts 1-6).

Schena challenges (Br.47-57) testimony that healthcare insurers require that providers follow applicable laws, including anti-kickback provisions, and describing what cooperating witnesses told Schena about EKRA. The district court did not plainly err in admitting this testimony.

A. Background

1. The government presented testimony from Stephen Quindoza, an expert on Medicare rules and regulations. 2-ER-368. Quindoza testified that Medicare policy requires that providers follow applicable laws including the Anti-Kickback Statute. 2-ER-396. He stated that "[h]ypothetically speaking," if a provider did not comply with those rules, Medicare would deny the claim. 2-ER-396-397. When the prosecutor asked, "[a]nd when does [the Anti-Kickback Statute] apply?", defense counsel objected: "Foundation. Calls for a legal argument or statement." 2-ER-397-398. Offering to lay a foundation, the prosecutor elicited testimony that Quindoza was familiar with the

[6] Schena is incorrect (Br.46) that this theory is "at odds" with Jablonski's prosecution. Jablonski pled guilty to conspiring to defraud the United States and to pay and receive illegal kickbacks to induce referrals. 3-ER-617; *see* No. 21-cr-213, Dkt.16 at 17-20 (N.D. Cal.) (factual basis). Schena is also incorrect in suggesting, for the first time (Br.46-47), a variance based on kickbacks paid to Mohan and Taguchi. The superseding indictment charged Schena with paying kickbacks to marketers and "other individuals." 2-ER-312, 314-315.

laws that Medicare considers for its kickback requirement. 2-ER-397-398. Quindoza then testified that Medicare policy refers to the Anti-Kickback Statute, which he said prohibits kickbacks to induce referrals. 2-ER-397-398. Quindoza said that "Medicare's policy" is not just for "kickbacks received by doctors" and that, "in Medicare's view," a kickback includes "a laboratory payment to a marketer for the purpose of referring … medical testing to the laboratory." 2-ER-400. In response to another hypothetical, Quindoza stated that "[i]f Medicare found out that the provider was paying kickbacks," then "Medicare should not pay those claims." 2-ER-401. Finally, Quindoza clarified that EKRA "applies to private insurance." 2-ER-399-400. On redirect, after Quindoza stated that his knowledge "extend[ed] to when EKRA applies," the prosecutor asked, "when does EKRA apply?" and Quindoza responded that EKRA is "the same" as the Anti-Kickback Statute but for other services. 2-ER-464-465. Defense counsel did not renew the initial objection, make a new objection, or request a limiting instruction.

The government also presented testimony from Alex Kondratenko, a Blue Shield fraud investigator. 7-ER-1865-1866. Kondratenko testified that "Blue Shield is aligned with state and federal law" and "considers kickbacks unlawful." 7-ER-1875. Kondratenko described a kickback as "basically giving someone something of value in return for a patient referral" and stated that "a lab payment to a marketer in exchange for the marketer referring patients to the lab" would qualify. 7-ER-1876. In response to a hypothetical, Kondratenko said that Blue Shield would not pay a claim if it learned

that "a lab had paid marketers a percentage of [Blue Shield]'s reimbursement in exchange for referred services." 7-ER-1877. Defense counsel did not object.

2. During his opening, defense counsel previewed testimony that an Arrayit employee had consulted a "respected law firm" and "told people … everything was okay." 2-ER-352. In the government's case-in-chief, three cooperating witnesses described their understanding of EKRA and how they conveyed that understanding to Schena. 2-ER-476, 489-491; 3-ER-639, 761; 5-ER-1223-1225. During that testimony, the district court sustained objections to broad questions. 2-ER-491 ("And did that become illegal under EKRA?"); 3-ER-641 ("[D]id that violate EKRA?"). The prosecutor rephrased the questions to focus on the witness's understanding. 2-ER-491 ("Was it your understanding that [EKRA] impacted Arrayit's 1099 networks?"); 3-ER-641 ("And was it your understanding that that violated EKRA?"). Counsel did not object to the rephrased questions or request a limiting instruction.

Consistent with his opening, defense counsel cross-examined witnesses on the law-firm advice, eliciting testimony that witnesses did not know what the firm told Schena, 2-ER-537, or that others said that the firm advised that EKRA would be overturned, 3-ER-639-640, 737-738. Outside the jury's presence, counsel disclaimed an advice-of-counsel defense but insisted that testimony referring to legal advice was admissible as the "inverse" of what the cooperators had told Schena about EKRA—evidence that counsel described as "clearly admissible" for the purpose of whether "Schena knew it was unlawful." 4-ER-1090, 1093.

3. The district court told the jury that "it is my duty to instruct you on the law" and it is "your duty to apply the law as I give to it to you." 1-SER-64. The court instructed on the elements of EKRA. 1-SER-90-91. The court further stated that expert-witness testimony "should be judged like any other testimony" and that the jury "may accept it or reject it and give it as much weight as [the jury] think[s] it deserves." 1-SER-75.

B. Standard of Review

A preserved evidentiary objection is reviewed for abuse of discretion. *See United States v. Alahmedalabdaloklah*, 94 F.4th 782, 835 (9th Cir. 2024). An evidentiary issue is not preserved when a party "fail[s] to make a specific objection" or "make[s] the *wrong* specific objection." *United States v. Gomez-Norena*, 908 F.2d 497, 500 (9th Cir. 1990). An unpreserved objection is reviewed for plain error. *Id.* "Plain error is (1) error, (2) that is plain, and (3) that affects substantial rights." *United States v. Depue*, 912 F.3d 1227, 1232 (9th Cir. 2019) (en banc). "If these conditions are met, the reviewing court has the discretion to grant relief so long as the error 'seriously affects the fairness, integrity, or public reputation of judicial proceedings.'" *Id.* The "burden of establishing entitlement to relief for plain error is on the defendant," *United States v. Dominguez Benitez*, 542 U.S. 74, 82 (2004), and "[m]eeting all four prongs is difficult, 'as it should be,'" *Puckett v. United States*, 556 U.S. 129, 135 (2009).

Schena failed to preserve these objections, and the Court should review the admission of this testimony for plain error. With respect to the insurer policies, Schena

objected only once, during Quindoza's direct examination, when a prosecutor asked the broad question, "When does [the Anti-Kickback Statute] apply?," 2-ER-397, and did not object at all during Kondratenko's testimony, *see* Br.52. This single objection, which appeared to have been resolved by additional foundation, did not preserve Schena's current argument. Defense counsel's limited objections during the cooperators' testimony also did not alert the district court that Schena objected to the cooperators describing their own understanding of EKRA and how they relayed that understanding to Schena. Counsel objected only to broad questions and did not object to rephrased questions asking about the witness's understanding of EKRA. 2-ER-491; 3-ER-641. Counsel's admission that this testimony was "clearly admissible" for knowledge confirms that Schena did not raise a broader objection. 4-ER-1093.

In these circumstances, the Court should not excuse (Br.52-53) Schena's failures to object. The district court responded to the limited objections by having the government lay additional foundation or ask a different question, or by sustaining the objection. That is a far cry from scenarios with "no possibility of a different ruling on a renewed objection." *United States v. Varela-Rivera*, 279 F.3d 1174, 1177-1178 (9th Cir. 2002).

C. The district court did not err, much less plainly err, in admitting this testimony.

The district court did not commit plain error in admitting this testimony. No witness offered a "legal conclusion" as to whether Schena's conduct did or did not meet

an element of the charged offenses. *Cf. United States v. Diaz*, 876 F.3d 1194, 1197 (9th Cir. 2017) ("Consistent with Rule 704(a), this court has repeatedly affirmed that 'an expert witness cannot give an opinion as to her *legal conclusion*, i.e., an opinion on an ultimate issue of law.'"). And at no point did any witness purport to instruct the jury on the applicable law for Schena's offenses.

Although the testimony referred to legal concepts, the witnesses referenced those concepts in discussing insurance policies or conversations with Schena—testimony that was clearly relevant to the jury's factual findings. In each instance, the government tailored its questions to elicit information about legal concepts only insofar as those concepts informed the jury about relevant factual disputes. For their part, Quindoza and Kondratenko described Medicare and Blue Shield policies, which were directly relevant to whether Schena defrauded those programs. *See United States v. Galatis*, 849 F.3d 455, 462 (1st Cir. 2017) (no error in expert testimony that described Medicare's regulatory framework "without displacing the district court's role in instructing the jury as to that framework's legal significance"). The cooperating witnesses described how they told Schena about their own understanding of EKRA—testimony that was directly relevant to Schena's intent, which Schena's opening statement put into dispute. *Cf. United States v. Kaplan*, 490 F.3d 110, 121 (2d Cir. 2007) ("Evidence of others' knowledge would have been highly relevant had it been supplemented by evidence supporting the conclusion that such knowledge was communicated to [the defendant.]"). In these

circumstances, the district court did not err by admitting the testimony. And any conceivable error was certainly not clear or obvious on this record.

Schena also cannot show that any error affected his substantial rights, much less the proceeding's fairness, integrity, or public reputation. To the extent that the witnesses discussed legal concepts, they did so accurately and consistent with the later-given jury instructions. Additionally, the district court instructed the jury to follow the court's instructions on the law and explained how to evaluate witness testimony. 1-SER-69, 75, 90-91. This Court presumes that the jury followed those instructions. *See United States v. Olano*, 507 U.S. 725, 740 (1993).

Finally, the trial documented overwhelming evidence of Schena's guilt, including his lies to insurers about Arrayit's regulatory approvals; deceptive marketing to promote Arrayit's blood-allergy test; the conspiracy to always test for 120 allergens without regard to individual need; the strategy to bundle allergy tests with COVID tests; and paying illegal kickbacks to induce referrals. *See supra* pp. 4-13. Moreover, after EKRA went into effect, Schena helped create a new written contract for Arrayit's marketers that accurately described EKRA but conspicuously omitted how Arrayit paid the marketers. 5-ER-1227-1228, 1230. Even if the district court had excluded the disputed testimony, no reasonable probability of an acquittal exists.

III. The district court did not plainly err in instructing the jury on the required mental state for the healthcare-fraud and EKRA violations (Counts 1-6).

Schena claims (Br.57-66) that the district court erred when instructing on the required mental state for the healthcare-fraud and EKRA charges because it included a sentence in the definition of "knowingly" stating that "knowingly" does not require proof "that the defendant knew that his acts or omissions were unlawful." This claim lacks merit.

A. Background

1. During a charge conference, the district court discussed the parties' proposed instructions, including the definitions of "knowingly" and "willfully" for the healthcare-fraud and EKRA charges.

With respect to "knowingly," the government proposed the Ninth Circuit pattern instruction: "An act is done knowingly if the defendant is aware of the act and does not act or fail[s] to act through ignorance, mistake, or accident. The government is not required to prove that the defendant knew that his acts or omissions were unlawful. You may consider evidence of the defendant's words, acts, or omissions, along with all the other evidence, in deciding whether the defendant acted knowingly." 1-SER-156; *see* Manual of Model Criminal Instructions ("Model Instructions") 4.8 (2022 ed.). As relevant here, Schena's proposal omitted the second sentence: "The government is not required to prove that the defendant knew that his acts or omissions were unlawful." 1-SER-219. A comment to the pattern instruction states that this

"sentence … should not be given when an element of the offense requires the government to prove that the defendant knew that what the defendant did was unlawful." Model Instructions 4.8 cmt.

During the charge conference, there was no discussion of the sentence, "The government is not required to prove that the defendant knew that his acts or omissions were unlawful." The parties and the district court did discuss the fact that the instructions defined knowingly in a different way for the securities-fraud offenses—*i.e.,* the instructions contained "two knowinglies." 8-ER-2128. Recognizing the potential confusion, all agreed that the scienter definitions should be "as close as possible to the counts they're relevant to." 8-ER-2128. Thus, in the final instructions, the scienter definitions for the healthcare-fraud and EKRA counts appeared directly after the instructions for those counts, and the scienter definitions for the securities-fraud counts were embedded into the instructions for those counts. 1-SER-94-96. The court also adopted defense counsel's suggestion to add language at the beginning of each scienter definition specifying the counts to which it applied. 8-ER-2130; 1-SER-94-96. Beyond those matters, the court said, "I'll otherwise give the model." 8-ER-2129.

With respect to "willfully," the government initially did not provide a definition. 1-SER-108-173; *see* Model Instructions 4.6 (declining to provide generic instruction). During the conference, the government proposed a definition that paraphrased Ninth Circuit law. 8-ER-2148. The court directed the parties to meet and confer and then

decided to instruct using the government's definition "incorporating in" the parties' comments. 8-ER-2148, 2289.

At the end of the discussion, the court directed the government to distribute an updated draft. 8-ER-2292. The record does not reflect additional objections.

2. Following closings, the district court charged the jury. 9-ER-2488. Immediately after instructing on the elements for healthcare fraud and EKRA, the court defined the terms knowingly and willfully as follows:

> With respect to the terms "knowing" or "knowingly" as used in the instructions for Counts One through Six, an act is done knowingly if Mr. Schena was aware of the act and does not act or fail to act through ignorance, mistake, or accident. The government is not required to prove that Mr. Schena knew that his acts or omissions were unlawful. You may consider evidence of Mr. Schena's words, acts, or omissions, along with all the other evidence, in deciding whether Mr. Schena acted knowingly.
>
> …
>
> With respect to the term "willfully" as used in the instructions for Counts One through Six, an act is done willfully if Mr. Schena acted with a bad purpose, that is, with general knowledge that his conduct was unlawful. The government need not prove that Mr. Schena was aware of the specific provision of the law that rendered his conduct unlawful.

1-SER-94-95. The court separately defined the terms knowingly and willfully when discussing the securities-fraud counts and specified that those definitions were "[f]or purposes of Counts Seven through Nine." 1-SER-96.

The court then asked for objections and there were none. 9-ER-2515.

3. During deliberations, the jury sought clarification on the meaning of "willfully" and "material" and how those terms differed between the counts. 2-ER-

279. With agreement from the parties, the district court pointed to the definitions in the jury charge. 2-ER-280; 9-ER-2544. The jury later asked if "'willful' include[s] 'knowing'" and if it is "possible to be 'willful' but not 'knowing.'" 2-ER-283. Outside the presence of the jury, the government noted, "I think they're asking if knowingly is subsumed by the concept of willfully" and that "the confusion may arise" because the willfully definition "refer[s] to the concept of knowledge." 9-ER-2547-2548. With agreement from the parties, the court directed the jury to the relevant definitions for knowingly and willfully. 2-ER-284; 9-ER-2549-2550. The court also reiterated to the jury that "[t]he Government must prove each element of each offense as indicated in the instructions for each offense charged." 2-ER-284.

B. Standard of Review

When an objection is preserved, this Court "review[s] de novo whether a jury instruction misstates the law." *United States v. Rodriguez*, 971 F.3d 1005, 1012 (9th Cir. 2020). The Court "must determine whether the instructions, viewed as a whole, were misleading or inadequate to guide the jury's deliberation." *United States v. Lonich*, 23 F.4th 881, 898 (9th Cir. 2022) (quotations omitted), *overruled on other grounds by United States v. Lucas*, 101 F.4th 1158 (9th Cir. 2024) (en banc). "Jury instructions, even if imperfect, are not a basis for overturning a conviction absent a showing that they prejudiced the defendant." *Id.*

If a defendant does not object, this Court reviews the instruction for plain error. *See United States v. Delgado*, 357 F.3d 1061, 1065 (9th Cir. 2004). To obtain relief, he

must show (1) error, (2) that is plain, (3) that affects substantial rights, and (4) that seriously affects the proceeding's fairness, integrity, or public reputation. *See supra* p. 34.

Schena's claim should be reviewed for plain error because counsel did not "inform the court of the specific objection" or "the grounds for the objection." *See United States v. Peterson*, 538 F.3d 1064, 1071 (9th Cir. 2008). That Schena's original proposal omitted this sentence also did not preserve an objection. *See United States v. Klinger*, 128 F.3d 705, 710 (9th Cir. 1997) (recognizing that the "mere proposal of an alternate instruction" does not preserve instructional dispute). As Schena points out (Br.30), "[n]either the court, nor counsel for either party, appears to have noticed" the sentence in the knowingly definition that he now disputes.

Schena wrongly asserts (Br.62) that he was excused from objecting after the district court said it would "give the model." 8-ER-2129. That statement did not convey the court's intent to omit the disputed sentence. And because the court's remark occurred before any discussion of willfulness, it also was unclear at that time whether the Model Instruction commentary advising omission of the disputed sentence applied to this case. *Cf.* Model Instructions 4.8 cmt. (giving as examples criminal copyright infringement and Lacey Act, a law related to fish and wildlife trafficking, *see* 16 U.S.C. § 3371). Defense counsel also did not object after the court charged the jury notwithstanding an invitation to do so. 9-ER-2515. These circumstances are therefore unlike *United States v. Liu*, 731 F.3d 982 (9th Cir. 2013), cited by Schena (Br.62), in which

a defendant proposed the correct instruction, objected to the incorrect instruction during the charge conference, received a draft with the correct instruction, and then had no opportunity to object after the court delivered the wrong instruction. 731 F.3d at 987-988.

C. The district court did not err, much less plainly err, because it correctly instructed the jury that a guilty verdict required findings that Schena acted knowingly and willfully.

1. The district court instructed the jury that a guilty verdict required findings that Schena committed the healthcare fraud and EKRA offenses *both* knowingly and willfully, and it correctly defined each of those terms. The disputed sentence from the pattern instruction in the definition of knowingly may have been inartful in this case, but it was not reversible error given the accompanying instructions requiring that the government also prove that Schena acted willfully.

The district court correctly defined knowingly and willfully. A "general 'knowingly' instruction addresses *knowledge of unlawful activity*" and "clarif[ies] that knowledge of an *act* 'does not include knowledge of the *law*.'" *United States v. Greer*, 640 F.3d 1011, 1020 (9th Cir. 2011). The court's definition did those things. It told the jury that "an act is done knowingly if Mr. Schena was aware of the act" and that the "government is not required to prove that Mr. Schena knew that his acts or omissions were unlawful." 1-SER-95. With respect to willfully, Schena agrees (Br.62) that the court "correctly stated the law" in defining willfulness as "act[ing] with a bad purpose, that is, with general knowledge that his conduct was unlawful." 1-SER-94. Importantly,

the court repeatedly emphasized that a guilty verdict required findings that Schena acted *both* knowingly and willfully. 1-SER-81, 84, 88, 90, 92 (instructions); 2-ER-284 (response to jury's note emphasizing requirement to prove each element).

Given these instructions, a jury could have found Schena guilty only if it concluded that he committed these offenses knowingly *and* willfully. This Court has consistently affirmed jury instructions that use a general definition of knowingly so long as the district court *also* separately instructs on willfulness, and it should do the same here. *See United States v. Solakyan*, --- F.4th ---, No. 22-50023, 2024 WL 4341365, at *11-12 (9th Cir. Sept. 30, 2024) ("disagree[ing]" with defendant's claim that disputed portion of knowingly definition was "impermissibly confusing" when accompanied by correct willfulness instruction); *Lonich*, 23 F.4th at 901 (finding that "nothing in the general 'knowingly' instruction—relating to whether 'an act is committed knowingly'—undermined the specific mens rea requirements applicable to misapplication of bank funds"); *United States v. Gallegos-Lopez*, 357 F. App'x 103, 104 (9th Cir. 2009) (observing that "[k]nowledge and intent are separate and distinct" and finding no error where "different instructions … adequately explained" requisite intent).

Schena is also incorrect (Br.57, 60) in asserting a "direct conflict" between the knowingly and willfully definitions that "negated" willfulness. These different words mean different things. *See Greer*, 640 F.3d at 1019-1020 (describing concepts as "thematically similar" but "substantively different because they address two distinct types of subjective knowledge"). Moreover, at defense counsel's suggestion, the district

court expressly clarified that each definition was "[w]ith respect to" its corresponding scienter element. 1-SER-94-95. This Court has found that similar language resolves any potential confusion among scienter definitions. *See, e.g., Lonich*, 23 F.4th at 899 (finding it helpful that knowingly definition began with phrase "to prove that an act is committed knowingly …") (emphasis omitted); *see also United States v. Knapp*, 120 F.3d 928, 932 (9th Cir. 1997) (noting that court limited definition "to money laundering").

The record reflects that these instructions adequately informed the jury that willfulness was required. The parties correctly described the scienter requirements in closing arguments. 9-ER-2370-2371 (prosecutor stated that "knowingly essentially means that the defendant knew what he was doing" whereas "acting willfully" means "with the general purpose of doing something unlawful"); 9-ER-2435, 2442 (defense counsel described "willfulness" as "general knowledge that the conduct was unlawful" and stated "on the issue of willfulness … [t]he government has to prove a general knowledge that this was unlawful"). *See United States v. Anderson*, 741 F.3d 938, 948 (9th Cir. 2013) (citing closing arguments). The jury's notes additionally reflected its understanding that willfulness was required, and the district court's responses directed the jury to the correct definitions and emphasized that the government must prove each element. 2-ER-279, 283-284.

2. Reversal is particularly unwarranted with respect to Counts One through Four because, in addition to the willfulness instructions, the district court also delineated the specific mental states required for these offenses.

Counts One and Four charged conspiracies. Consistent with long-standing conspiracy principles, the district court properly directed the jury to focus on specific intent. *See Ocasio v. United States*, 578 U.S. 282, 288 (2016) (observing that conspiracies require "an agreement with the 'specific intent that the underlying crime be committed' by some member of the conspiracy") (emphasis omitted). Specifically, the court explained that a conspiracy is "the agreement to do something unlawful"; that "[o]ne becomes a member of a conspiracy by willfully participating in the unlawful plan with the intent to advance or further some object or purpose of the conspiracy"; and that the objects were "to commit health care fraud or wire fraud" (Count 1) and "to pay illegal kickbacks" (Count 4). 1-SER-81, 90. Similarly, with respect to the healthcare-fraud charges in Counts Two and Three, the court instructed that a guilty verdict required the jury to find that "Schena acted with the intent to defraud," which it defined as "an intent to deceive and cheat." 1-SER-88-89.

The specific intent applicable to these counts dovetails with willfulness. Because the jury understood that Schena could be guilty of these offenses only if he agreed to an unlawful plan with intent to further an unlawful object (conspiracy) or if he intended to deceive and cheat (healthcare fraud), these instructions adequately explained that Schena could be guilty only if he acted with a bad purpose. *See Solakyan*, 2024 WL 4341365, at *11-12 (noting that instructions on specific-intent requirement clarified scienter requirement even where knowingly definition included the disputed sentence); *United States v. Awad*, 551 F.3d 930, 940 (9th Cir. 2009) ("No reasonable jury could have

found that a physician intended to deceive or cheat the Federal Government but did not know that such conduct is unlawful, especially in light of the warnings on the claim forms.").

3. Schena refers (Br.59-60, 63) to confusion between the scienter requirements for the healthcare-fraud and EKRA offenses and the securities-fraud offenses. This is a red herring. These instructions were crystal clear as to which definition applied to which offense. The district court placed the scienter definitions either next to or in the instructions for the applicable offenses and introduced each definition with language clearing identifying the relevant counts. 1-SER-94-96. Courts presume that the jury follows the district court's instructions. *See Olano*, 507 U.S. at 740. Indeed, the jury's note and the court's response reflected the understanding that the "meaning is different for counts 1-6 and 7-9." 2-ER-279-280; *see also* 9-ER-2370, 2389 (prosecutor and defense counsel noting difference in definitions during closing arguments). Schena is therefore incorrect (Br.63) that a juror considering the overall charge would "assume" a "majority rule" that "knowledge of unlawfulness was not required" (emphasis omitted).

4. At a minimum, any error in the court's inclusion of the disputed sentence in the definition of knowingly was not "clear" or "obvious" in these circumstances. "An error cannot be plain where there is no controlling authority on point and where the most closely analogous precedent leads to conflicting results." *United States v. Gonzalez Becerra*, 784 F.3d 514, 518 (9th Cir. 2015). "Imprecision … is not the

equivalent of clear and obvious error." *Anderson*, 741 F.3d at 948. *Cf. Bryan v. United States*, 524 U.S. 184, 199 (1998) (finding that "misstatement of the law" on willfulness given after correct instruction did not support reversal).

Moreover, any error also did not affect Schena's substantial rights and was harmless beyond a reasonable doubt. As discussed above, in addition to the willfulness instruction, the district court's instructions on Counts One through Four separately included mental-state instructions requiring the jury to find that Schena acted with a bad purpose. Consequently, any instructional error in Counts Five and Six was necessarily harmless because by finding Schena guilty of conspiring to violate EKRA, the jury necessarily found that Schena had a bad purpose in committing acts in furtherance of that conspiracy. *See United States v. Fei Lin*, 139 F.3d 1303, 1309 (9th Cir. 1998) (finding instructional error harmless where "jury was instructed with respect to specific intent in connection with the conspiracy" and therefore "necessarily found the requisite specific intent" for the objects of that conspiracy). *Cf. United States v. Lindsey*, 634 F.3d 541, 555 (9th Cir. 2011) (finding that failure to give a conspiracy instruction requiring overt act was harmless because guilty verdict on substantive counts was "'functionally equivalent' to finding the existence of the overt act element").

Finally, the government adduced overwhelming evidence that Schena knew that his actions were unlawful. With respect to the healthcare fraud counts, the certifications in Schena's paperwork for Medicare and other health-insurance programs required Arrayit to provide true and accurate information and to follow applicable laws. 2-ER-

388, 395-398; 7-ER-1868-1869. But Schena lied to get Arrayit's regulatory approvals, lied about Arrayit's allergy test and ignored warnings that it was not medically necessary, paid illegal kickbacks, and bundled lucrative allergy tests with COVID tests regardless of what patients wanted or needed. *See supra* pp. 4-13. Arrayit's allergy-test Medicare billings were "wildly out of line" with every other laboratory, and no reasonable person could have thought they were lawful. *See Awad*, 551 F.3d at 941.

With respect to the EKRA counts, Schena ignored repeated warnings that kickbacks to induce referrals were illegal under EKRA, and he created a sham contract to hide those payments. 2-ER-494; 3-ER-761-762; 5-ER-1227-1228, 1230. And with respect to Counts Five and Six, the jury separately heard overwhelming evidence of Schena's guilt on an independent theory of vicarious liability because Schena's co-conspirator, Jablonski, received the payments charged in Counts Five and Six despite knowing that these kickbacks violated EKRA. 3-ER-617, 638-644; 1-SER-93 (co-conspirator instruction based on *Pinkerton v. United States*, 328 U.S. 640 (1946)). *See United States v. Ajayi*, 64 F.4th 243, 248 (5th Cir. 2023) (per curiam) (finding any instructional error harmless in light of conspiracy instruction and *Pinkerton* charge).[7]

[7] Schena has not challenged the district court's instruction on co-conspirator liability. *See United States v. Roselli*, 432 F.2d 879, 895 (9th Cir. 1970) ("A conspirator, however, may be convicted on the *Pinkerton* theory without a specific allegation that a coconspirator committed the offense in furtherance of the conspiracy.").

IV. Sufficient evidence supports Schena's securities-fraud convictions (Counts 7-9).

Schena asserts (Br.66-72) insufficient evidence to support his securities-fraud convictions. That is incorrect.

A. Standard of Review

As Schena concedes (Br.72), this Court's review is restricted to plain error because he did not raise this claim before the district court. *See United States v. Lopez*, 4 F.4th 706, 719 (9th Cir. 2021) ("While Rule 29 motions need not specify grounds for acquittal, it is well established that Rule 29 motions raising particular grounds fail to preserve appellate review of other grounds not raised."). Schena must show error, that was plain, that prejudiced his substantial rights. *Id.* This Court "overturn[s] a conviction for plain error resulting in insufficient evidence only to prevent a miscarriage of justice or to preserve the integrity and the reputation of the judicial process." *Id.* (quotations omitted).

B. Discussion

Section 10(b) of the Securities Exchange Act of 1934 makes it unlawful to "use or employ, in connection with the purchase or sale of any security … any manipulative or deceptive device or contrivance in contravention of such rules and regulations as the [Securities and Exchange Commission] may prescribe." 15 U.S.C. § 78j(b). SEC Rule 10b-5 implements that provision by making it unlawful for issuers for registered securities to "make any untrue statement of a material fact or to omit to state a material

fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading." 17 C.F.R. § 240.10b-5(b). In *Basic Inc. v. Levinson*, 485 U.S. 224, 231 (1988), the Supreme Court held that Rule 10b-5 cases are governed by the standard that a "fact is material if there is a substantial likelihood that a reasonable shareholder would consider it important in deciding how to vote." The district court correctly instructed the jury on that standard, 1-SER-97, and the verdict is amply supported by the trial evidence. At a minimum, the verdict is not a miscarriage of justice.

With respect to Count Seven, the November 2018 Sutter Health release did more than simply "suggest[]" (Br.67) an agreement. The press release "announce[d] an allergy testing agreement with Northern California health care leader Sutter Health." 3-ER-813-814. Schena does not dispute that this was a lie. 4-ER-1040-1041, 1051. With respect to Count Eight, Schena also does not dispute that the August 2019 tweet announcing a $240-million manufacturing run was a lie. 8-ER-2213-2214, 2218-2219. As the trial evidence showed, investors relied on Arrayit's public statements because little other publicly available information existed about the company. 4-ER-958; 5-ER-1346-1347. The manufacturing-run tweet was especially relevant because it purported to provide information about Arrayit's financial state in the absence of financial statements. 6-ER-1627. The tweet's materiality is further evidenced by emails that Schena received asking for specific confirmation of the $240-million figure. 3-ER-823-828. Finally, with respect to Count Nine, Schena is incorrect (Br.69) that the March

2020 emails made "clear that Arrayit was in the process of rolling out its COVID test" (emphasis omitted). The emails referred to "more than 50,000 requests for our fingerstick blood test for [COVID-19]" and stated that Arrayit was working to make the test available. 4-ER-874-875. Particularly viewing this evidence in the light most favorable to the verdict, a reasonable investor reading that sentence would believe that Arrayit had received 50,000 requests for an existing COVID test and that Arrayit was "rolling out" its distribution. But these emails reported false information. Arrayit had received only 842 emails about COVID-19; it had been shipped the proteins needed to develop a test only two days prior; and it lacked any data on test validity. 4-ER-880-881; 5-ER-1257; 6-ER-1563, 1568-1570.

V. The district court did not clearly err in calculating restitution and forfeiture.

Schena challenges (Br.72-76) the restitution and forfeiture calculations. These arguments fail.

A. Background

The Probation Office's Presentence Report (PSR) recommended $99 million of intended loss under Sentencing Guideline § 2B1.1, corresponding to $77 million in claims billed to insurance for healthcare fraud and $21.5 million in loss for securities fraud. PSR ¶¶ 49-50, 60. The PSR also recommended restitution of $24.2 million, corresponding to actual loss of $2.7 million in paid insurance claims and $21.5 million

lost by investors, and a forfeiture judgment for proceeds traceable to the offense. *Id.* ¶¶ 111-114.[8]

With respect to healthcare fraud, the trial testimony established that Arrayit billed healthcare insurers over $77 million and that insurance paid Arrayit over $2.7 million. 8-ER-2179-2181. With respect to securities fraud, the government's expert submitted spreadsheets calculating loss for individual shareholders between the onset of Schena's fraud (July 15, 2015) and the date the SEC suspended trading (April 14, 2020). 1-SER-20-21; 2-SER-268-272, 286-319. The expert calculated loss by first, excluding non-victim accounts; second, applying a first-in/first-out methodology (assuming that the first share sold was the first share bought); and third, using the share's sale price or, if the share had not been sold by the suspension of trading, $0. 2-SER-268-269. The expert explained that he used the first-in/first-out method rather than the modified-rescissory method (*i.e.*, the difference between the average stock price during the fraud and after its disclosure) because the stock was thinly traded, and Schena owned a significant number of shares. 2-SER-269-270. Application Note 3(F)(ix) to Guideline § 2B1.1 explains that a court determining loss "may use any method that is appropriate

[8] Although the PSR purports to relay the government expert's calculations of investor loss, it contains minor discrepancies as compared to the underlying documentation. For convenience, this description uses the figures appearing in the underlying source material. 2-SER-272.

and practicable under the circumstances" and that "[o]ne such method the court may consider" is the modified-rescissory method.

In calculating loss under the Sentencing Guidelines, the district court concluded that the government had not met its burden under a clear-and-convincing standard. 1-ER-22, 29. With respect to healthcare fraud, the district court stated that it "ha[d] no qualms with a general finding that [Schena's] conduct of conviction resulted in losses—indeed, quite substantial ones—to health care insurers" but that under the clear-and-convincing standard, it "struggled" because the government had not proven the loss attributable to fraud. 1-ER-28-29. Accordingly, the court rejected "a loss calculation that results in a life sentence." 1-ER-23. With respect to securities fraud, the court concluded that the government's expert used "too broad of a brush" to satisfy the clear-and-convincing standard. 1-ER-20. The court stated that the expert's declaration did not adequately explain how Schena's fraud affected Arrayit's stock, the first-in/first-out methodology, or a $0 close-out price. 1-ER-20-22.

In calculating restitution, the district court determined that the government proved actual loss of $24,289,540.95 by a "preponderance of the evidence." 1-ER-11-13. The court emphasized that "restitution" and the "Guidelines" are "two very different things and serve very different purposes" and that restitution requires proof only by the preponderance standard. 1-ER-12, 228. Under that lower standard, the court found that the government's healthcare and securities-fraud loss calculations were "well-founded"; that "even [Schena] acknowledged" that insurers paid Arrayit $2.7

million; and that "[t]he specific amounts enumerated in the Government's spreadsheet established … both the specific investor victims and the full amounts of their losses with 'some reasonable certainty.'" 1-ER-12-13. The court also ordered a forfeiture-money judgment of $2,727,240.14 corresponding to the proceeds generated by Schena's healthcare fraud. 1-ER-11, 233, 237-238.

B. Standard of Review

This Court reviews factual challenges to a district court's restitution and forfeiture findings for clear error. *See United States v. Dadyan*, 76 F.4th 955, 961 (9th Cir. 2023). To obtain relief, a defendant must go beyond "[b]road, unsupported contentions of inaccuracy" and instead "undermine the reliability of specific evidence" or the "specific factual underpinnings of the calculation." *Id.*

C. Schena fails to show clear error in the restitution and forfeiture calculations.

Schena's challenges (Br.72-75) to the restitution and forfeiture findings rely on the fact that the district court rejected the government's loss calculations for Guidelines purposes. But Schena's reliance on that ruling is misplaced. As the district court observed, Guidelines loss and restitution are "two very different things" that "serve very different purposes." 1-ER-228. *See Dadyan*, 76 F.4th at 959-960 (discussing differences). Thus, "[t]here is no categorical rule that restitution must be equal to or less than the amount of loss found when applying Sentencing Guidelines § 2B1.1(b)(1)." *Id.* at 959.

Schena's reliance on *this* Guidelines ruling is especially misplaced because the district court applied the clear-and-convincing standard. 1-ER-22. The court repeatedly emphasized that this heightened standard was central to its ruling. 1-ER-22, 23, 24, 29. Apart from being legal error, *see Lucas*, 101 F.4th at 1159 (holding that sentencing courts must apply preponderance standard for Guidelines enhancements), that the court used a more demanding standard confirms that its Guidelines loss analysis is not transferable to the restitution and forfeiture analysis under the lower preponderance standard. Indeed, this Court has "caution[ed] against overreliance on a discrepancy, as it does not indicate *which* figure, restitution or Guidelines loss, might be erroneous." *Dadyan*, 76 F.4th at 960.[9]

The record evidence confirms that the district court's restitution and forfeiture findings were "well-founded." With respect to healthcare-fraud loss, Schena argues (Br.75-76) that the government failed to show that Arrayit's testing was "worthless." However, the undisputed trial testimony established that insurers would not have paid these claims if they knew that Schena lied to get Arrayit's licenses; that Arrayit submitted false information to enroll; that Arrayit's test was medically unnecessary; or that Arrayit paid kickbacks. 2-ER-401, 412-413; 7-ER-1877. Therefore, the court did not clearly err in finding that the insurance claims were the result of Schena's fraud. *See United States v. Hunter*, 618 F.3d 1062, 1065 (9th Cir. 2010) (affirming loss calculation where

[9] Although the district court's Guidelines ruling contains a legal error, the government has not appealed it.

victims "did not get what they paid for" because defendant lacked nursing license); *United States v. DeHaan*, 896 F.3d 798, 808 (7th Cir. 2018) (on plain error, affirming loss calculation for services to fraudulently certified patients); *United States v. Jones*, 664 F.3d 966, 984 (5th Cir. 2011) (noting that "Medicare received no value from [treatments that did not meet its standards]"). Schena's assertion (Br.75) that "the government failed to establish that the testing services had no value" (emphasis omitted) does not demonstrate clear error and, in any event, is contrary to the evidence that Arrayit's tests were inaccurate and not medically necessary. *See supra* pp. 7-13.

With respect to investor losses, Schena asserts (Br.73-74) insufficient evidence to "link" stock prices to his fraud. The restitution statute defines "victim" as "a person directly and proximately harmed as a result of the commission of an offense." 18 U.S.C. § 3663A(a)(2). This proximate-cause inquiry "is often explicated in terms of foreseeability or the scope of the risk created by the predicate conduct." *Paroline v. United States*, 572 U.S. 434, 445 (2014). The district court did not clearly err in determining that Schena's conduct foreseeably affected Arrayit's stock prices. *Cf. United States v. Anieze-Smith*, 923 F.3d 565, 572 (9th Cir. 2019) (approving restitution for losses throughout fraudulent scheme). Other than the Guidelines ruling, Schena cites (Br.74) no evidence to substantiate his claim that not all investor losses were "attributable" to his fraud.

Schena also briefly asserts (Br.74-75) insufficient evidence that Arrayit stock was worthless by April 2020 and that the government did not adequately justify its expert's

methodology. But, again, Schena has not substantiated either claim. This case is thus unlike *United States v. Zolp*, 479 F.3d 715, 720 (9th Cir. 2007), *see* Br.74-75, in which the government "acknowledge[d]" that a stock retained value. Rather, as the district court found, the expert's spreadsheet detailing individual investments "contained sufficient detail" to "establish[], by a preponderance of the evidence, both the specific investor victims and the full amounts of their losses with 'some reasonable certainty.'" 1-ER-12.

CONCLUSION

This Court should affirm.

Respectfully submitted,

ISMAIL J. RAMSEY
United States Attorney

CHRISTINA LIU
Assistant United States Attorney
Northern District of California

JACOB FOSTER
Principal Deputy Assistant Chief

LAURA CONNELLY
Trial Attorney
Fraud Section, Criminal Division

NICOLE M. ARGENTIERI
Principal Deputy Assistant Attorney General

LISA H. MILLER
Deputy Assistant Attorney General

/s/ Sofia M. Vickery
SOFIA M. VICKERY
Attorney, Appellate Section
Criminal Division
U.S. Department of Justice
950 Pennsylvania Ave., N.W.
Washington, DC 20530
(202) 305-7408
Sofia.Vickery@usdoj.gov

Attorneys for Plaintiff-Appellee
UNITED STATES OF AMERICA

Dated: October 23, 2024

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

Form 8. Certificate of Compliance for Briefs

Instructions for this form: http://www.ca9.uscourts.gov/forms/form08instructions.pdf

9th Cir. Case Number(s) 23-2989

I am the attorney or self-represented party.

This brief contains 13,925 **words,** excluding the items exempted by Fed. R. App. P. 32(f). The brief's type size and typeface comply with Fed. R. App. P. 32(a)(5) and (6).

I certify that this brief *(select only one)*:

[X] complies with the word limit of Cir. R. 32-1.

[ ] is a **cross-appeal** brief and complies with the word limit of Cir. R. 28.1-1.

[ ] is an **amicus** brief and complies with the word limit of Fed. R. App. P. 29(a)(5), Cir. R. 29-2(c)(2), or Cir. R. 29-2(c)(3).

[ ] is for a **death penalty** case and complies with the word limit of Cir. R. 32-4.

[ ] complies with the longer length limit permitted by Cir. R. 32-2(b) because *(select only one)*:
- [ ] it is a joint brief submitted by separately represented parties;
- [ ] a party or parties are filing a single brief in response to multiple briefs; or
- [ ] a party or parties are filing a single brief in response to a longer joint brief.

[ ] complies with the length limit designated by court order dated _____.

[ ] is accompanied by a motion to file a longer brief pursuant to Cir. R. 32-2(a).

Signature *s/ Sofia M. Vickery* **Date** October 23, 2024
*(use "*s/[typed name]*" to sign electronically-filed documents)*